

2055/0E203

U.S. Serial No. 08/594,175

Exhibit B

Declaration of Inventor David Watkins Under 37 C.F.R. § 1.132

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Atty. File No. 144-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Watkins, et al.

Serial No.: 08/594,175

Group Art Unit: 1508

Filed: January 31, 1996

Examiner: G. Kishore

For: LIPID VESICLES FORMED WITH ALKYLAMMONIUM
FATTY ACID SALTSTo: Assistant Commissioner of Patent and Trademarks
Washington, DC 20231**CERTIFICATE OF MAILING**I hereby certify that this correspondence
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Washington, DC 20231

on the date hereon.

(name)

(date)

AFFIDAVIT UNDER 37 CFR 1.132

Ass't Commissioner of Patents and Trademarks

Washington, DC 20231

Dear Sir:

Dr. David C. Watkins, a named inventor in the above-identified application, being
duly sworn, deposes and says:

1. That I am a doctor of Biochemistry, having received a D.Phil. in Biochemistry from
the University of Sussex, Brighton, United Kingdom in May 1984.

- Gao, P., Watkins, DC and Malbon, C.C. (1995) Constitutively active mutant $G_{s\alpha}$ (G225T) and null-mutant G_{i2} (G203T) induce primitive endoderm from stem cells. *Am. J. Physiol.* C1460-C1465
- Watkins, DC, Moxham, C.M., Morris, A.J. and Malbon, C.C. (1994) Suppression of G_{i2} enhances phospholipase C signaling. *Biochem. J.*, 299, 593-596
- Wang, H.Y., Watkins, DC and Malbon, C.C. (1992) Antisense oligodeoxynucleotides to G_i protein alpha-subunit sequence accelerate differentiation of fibroblasts to adipocytes. *Nature*, 358, 334-337
- Watkins, DC, Johnson, G.L. and Malbon, C.C. (1992) Regulation of the differentiation of teratocarcinoma cells into primitive endoderm by G_{i2} . *Science*, 258, 1373-1375
- Rapiejko, P.J., Watkins, DC, Ros, M. and Malbon, C.C. (1990) G-protein subunit mRNA levels in rat heart, liver, and adipose tissues: analysis by DNA-excess solution hybridization. *Biochem. Biophys. Acta* 1052, 348-350
- Guest, S.J., Hadcock, J.R., Watkins, DC and Malbon, C.C. (1990) Beta 1- and beta 2-adrenergic receptor expression in differentiating 3T3-L₁ cells. Independent regulation at the level of mRNA. *J. Biol. Chem.*, 265, 5370-5375
- Hadcock, J.R., Ros, M., Watkins, DC and Malbon, C.C. (1990) Cross-regulation between G-protein-mediated pathways. Stimulation of adenylyl cyclase increases expression of the inhibitory G-protein, G_i alpha 2. *J. Biol. Chem.*, 265, 14784-14790
- Galvin-Parton, P.A., Watkins, DC and Malbon, C.C. (1990) Retinoic acid modulation of transmembrane signaling. Analysis in F9 teratocarcinoma cells. *J. Biol. Chem.*, 265, 17771-17777.

11. That I am an inventor of this invention, which includes apparatus and process for preparing cationic liposomes (or CATEZOMESTM).

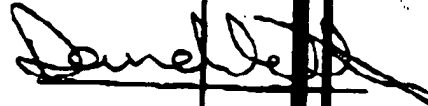
2. That I have done post-doctoral work under Dr. Craig C. Malbon for four (4) years in the field of Pharmacology from May 1984 through March 1988.
3. That I have been employed as an Instructor in the Department of Pharmacology at the State University of New York at Stony Brook for two (2) years from March 1988 through March 1990.
4. That I have been employed as a Research Assistant Professor of Pharmacology at the State University of New York at Stony Brook for three (3) years from March 1990 through March 1993.
5. That I have been employed by Collaborative Laboratories for one (1) year as Group leader of Biochemistry from March 1993 through May 1994.
6. That I have been employed by Collaborative Laboratories for three (3) years as Manager of Biochemical Services from May 1994 through May 1997.
7. That I have been employed by The Collaborative Group for nine (9) months as Director of Project Development.
8. That I have held the position of Adjunct Assistant Professor of Pharmacology at the State University of New York at Stony Brook for five (5) years from March 1993 through the present time.
9. That I have held the position of Director of Biochemistry at Clear Solutions Biotechnology for almost three (3) years since March 1995, through the present time.
10. That I have published numerous papers in the fields of Biochemistry and Pharmacology, including, but not limited to, the following:

Watkins, D.C., Assmann, M., Ansaldi, A. and Hayward, J.A. (1997)
Catezomes™: a novel delivery system for hair conditioning. *Cosmetics and Toiletries Manufacturing Worldwide*. Aston Publishing Group, Hemel Hempstead, UK.

Watkins, DC (1996) Liposomes: back to the future. *BioPharm* 9: 28.

12. That based on my recited experience in the field of liposomes and encapsulation technologies, I hold myself out as an expert in same field.
13. That cationic liposomes disclosed by this invention were not on sale, nor commercially used before January 10, 1996

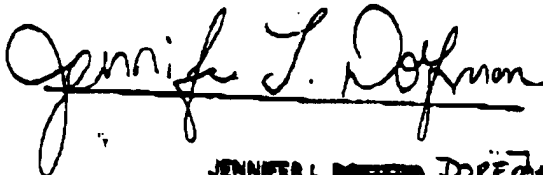
Dated: Stony Brook, NY



David Watkins

Co-Inventor

Sworn to before me this
16th day of February, 1998.



JENNIFER L. DORFMAN
Notary Public, State of New York
No. 0180498348
Qualified in Suffolk County
Commission Expires 7-16-98

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FATTY ACID SALTS

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Washington, DC 20231

RESPONSE

Sir:

In Response to and in furtherance of the February 6, 1998, telephone discussion between applicants' undersigned attorney and Examiner Gollamudi S. Kishore of the US Patent Office, applicants submit herewith a Declaration Under 37 CFR § 1.132, executed by inventor David Watkins, Ph.D., declaring that applicants' cationic liposomes, as disclosed by this pending application, have not been offered for sale, nor have they been used commercially, before January 10, 1996.

Further, applicants believe that the 1.132 Declaration by David Watkins, when viewed with applicant's prior Amendment mailed October 29, 1997 in this case, places claims 1-30 in condition for allowance, the same respectfully requested hereby.

Respectfully yours,

John F. Vodopia (Reg. No. 36,299)
460 New York Ave.
Huntington, NY 11743
(516) 271-2735 FAX 271-3361

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FAX TRANSMITTAL LETTER:

Date: 2/17/98 Please Deliver To: Examiner Kishore (1508)

FAX NO.: 704 308 7924 Re: 08/594,175

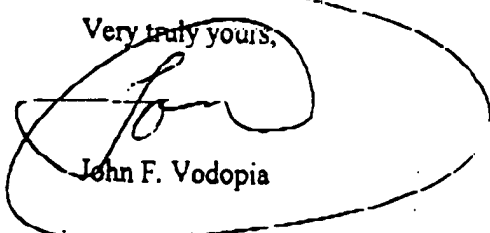
of pages including FAX cover sheet 6

Comments by Sender:

Dear Dr. Kishore:

Enclosed with this facsimile transmission
is the 1.132 Affidavit, executed by inventor Watkins,
asserting first use of the cationic liposomes

Very truly yours,


John F. Vodopia

PLEASE BE ADVISED that all information transmitted hereby is private and confidential.